

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1-28 (Canceled).

29 (Currently Amended). ~~An~~ A pH-independent extended release dosage form, comprising:

~~Venlafaxine Hydrochloride~~ venlafaxine hydrochloride in an amount of 30-60% based on the total weight of ~~said~~ the dosage form;

said ~~Venlafaxine Hydrochloride~~ venlafaxine hydrochloride being coated on a nonpareil inert core, said nonpareil inert core comprising 30-60% ~~of~~ based on the total weight of the dosage form;

the venlafaxine hydrochloride ~~Venlafaxine Hydrochloride~~ being optionally connected to a binder in a binder amount of 0.5-10% ~~of~~ based on the total weight of the dosage form;

a hydrophilic polymeric or glycerol monostearate (GMS) layer coating said venlafaxine hydrochloride ~~Venlafaxine Hydrochloride~~ and comprising 0.5-10% ~~of~~ based on the total weight of the dosage form; and

a ~~control~~ controlled release layer coated over said hydrophilic polymeric or GMS layer, said ~~control~~ controlled release layer comprising a hydrophobic polymer optionally mixed

with a plasticizer, said hydrophobic polymer comprising 2-15% ~~of~~
based on the total weight of the dosage form, and said optional
plasticizer, when present, comprising 0.1-2% ~~of~~ based on the
total weight of the dosage form;

said ~~control-controlled~~ release layer ~~constituting~~
~~means to control~~ permitting controlled release of the venlafaxine
hydrochloride ~~Venlafaxine Hydrochloride~~ over an approximately 24
hour period.

30 (Currently Amended). The unit dosage form of claim
29, wherein ~~comprising hydroxypropylmethylcellulose in~~ at least
one of said ~~additional polymeric-controlled release layer~~, said
hydrophilic polymeric or GMS layer, and said optional binder,
when present, comprises hydroxypropylmethylcellulose.

31 (Currently Amended). ~~An~~ A pH-independent extended
release composition, comprising:

a nonpareil inert core;

a venlafaxine hydrochloride ~~Venlafaxine Hydrochloride~~
layer coating said inert core, said venlafaxine hydrochloride
~~Venlafaxine Hydrochloride~~ comprising 30-60% ~~w/w~~ based on the
total weight of the composition; and

a hydrophobic polymer layer coating said venlafaxine
hydrochloride ~~Venlafaxine Hydrochloride~~ layer,

said hydrophobic polymer layer comprising 2-15%
~~w/w~~ based on the total weight of the composition,

said hydrophobic polymer layer enabling controlled
release of the venlafaxine hydrochloride ~~Venlafaxine~~
~~Hydrochloride~~ over an extended time period.

32 (Currently Amended). The composition according to claim 31, further comprising glycerol monostearate (GMS) or a hydrophilic polymer layer coating said venlafaxine hydrochloride ~~Venlafaxine Hydrochloride~~-layer, said GMS or hydrophilic polymer layer providing at least one function of isolating, protecting and separating the venlafaxine hydrochloride ~~Venlafaxine Hydrochloride~~-layer from the hydrophobic polymer layer.

33 (Currently Amended). The composition according to claim 32, wherein the GMS or hydrophilic polymer layer ~~is comprises a polymer~~ selected from the group consisting of polyvinylpyrrolidone, hydroxypropylcellulose, hydroxypropylmethylcellulose, microcrystalline cellulose, and carrageenan.

34 (Currently Amended). The composition according to claim 32, wherein the GMS or hydrophilic polymer layer is 0.5-10% ~~w/w~~ based on the total weight of the composition.

35 (Currently Amended). The composition according to claim 31, wherein the venlafaxine hydrochloride ~~Venlafaxine Hydrochloride~~-layer further comprises a binder.

36 (Currently Amended). The composition according to claim 35, wherein the binder is selected from the group consisting of ~~polyvinyl pyrrolidone~~ polyvinylpyrrolidone, hydroxypropylcellulose and hydroxypropylmethylcellulose.

37 (Currently Amended). The composition according to claim 35, wherein the binder is 0.5-10% ~~w/w~~based on the total weight of the composition.

38 (Currently Amended). The composition according to claim 31, wherein the hydrophobic layer further comprises a plasticizer.

39 (Currently Amended). The composition according to claim 38, wherein the plasticizer is 0.1-2% ~~w/w~~based on the total weight of the composition.

40 (Currently Amended). The composition according to claim 38, wherein the plasticizer is selected from the group consisting of castor oil, dibutyl sebacate, glyceryl monostearate, diethyl ~~phthalate~~phalate, glyceryl ~~triheptanoate~~triheptanoate, hydroxypropyl cellulose, polyethylene glycol, and triethyl citrate.

41 (Currently Amended). The composition according to claim 31, wherein the hydrophobic polymer layer comprises ~~ammonio methacrylate copolymer, Eudragit or a cellulose derivative selected from hydroxypropylmethylcellulose, ethyl cellulose, (such as ETHOCEL) and or cellulose acetate.~~

42 (Previously Presented). The composition according to claim 31, wherein the nonpareil inert core is an inert sugar core or a microcrystalline cellulose core.

43 (Currently Amended). The composition according to claim 42, wherein the core is 30-60% ~~w/w~~based on the total weight of said composition.

44 (Withdrawn/Currently Amended). In a method for administering ~~venlafaxine~~venlafaxine hydrochloride to a patient in need thereof, comprising administering the ~~venlafaxine~~venlafaxine hydrochloride as an extended release composition to the patient, the improvement wherein the extended release composition is in accordance with claim 31.

45 (Withdrawn/Currently Amended). A method for preparing an extended release composition in accordance with claim 31, comprising:
providing the nonpareil inert core+;
coating the nonpareil inert core with a layer of the ~~venlafaxine~~venlafaxine hydrochloride; and
coating the ~~venlafaxine~~venlafaxine hydrochloride layer with the hydrophobic polymer layer.

46 (New). The composition of claim 29, wherein the hydrophilic polymeric or GMS layer comprises polyvinylpyrrolidone, the hydrophobic polymer is ethyl cellulose and the controlled release layer further comprises a dibutyl sebacate plasticizer.

47 (New). A pH-independent extended release dosage form having dissolution characteristics that are equivalent to those of the venlafaxine hydrochloride dosage form sold under the proprietary name EFFEXOR XR, comprising:

venlafaxine hydrochloride in an amount of 30-60% based on the total weight of the dosage form;

said venlafaxine hydrochloride being coated on a nonpareil inert core, said nonpareil inert core comprising 30-60% based on the total weight of the dosage form;

the venlafaxine hydrochloride being optionally connected to a binder in a binder amount of 0.5-10% based on the total weight of the dosage form;

a hydrophilic polymeric or glycerol monostearate (GMS) layer coating said venlafaxine hydrochloride and comprising 0.5-10% based on the total weight of the dosage form; and

a controlled release layer coated over said hydrophilic polymeric or GMS layer, said controlled release layer comprising a hydrophobic polymer mixed with a plasticizer, said hydrophobic polymer comprising 2-15% based on the total weight of the dosage form, and said plasticizer comprising 0.1-2% based on the total weight of the dosage form;

the parameters being selected so as to control release of the venlafaxine hydrochloride over an approximately 24 hour period in a manner that is equivalent to the dissolution characteristics of EFFEXOR XR.

48 (New). The composition of claim 47, wherein the hydrophilic polymeric or GMS layer comprises polyvinylpyrrolidone, the hydrophobic polymer is ethyl cellulose and the controlled release layer further comprises a dibutyl sebacate plasticizer.